

## Food and Drug Administration, HHS

## § 808.59

when issued, as preempting a previously exempt State or local requirement.

(2) An exemption may be revoked upon a finding that there has occurred a change in the bases listed in § 808.20(c)(4) upon which the exemption was granted.

(3) An exemption may be revoked if it is determined that a condition placed on the exemption by the regulation under which the exemption was granted has not been met or is no longer being met.

(4) An exemption may be revoked if a State or local jurisdiction fails to submit records as provided in § 808.20(c)(6).

(5) An exemption may be revoked if a State or local jurisdiction to whom the exemption was originally granted requests revocation.

(6) An exemption may be revoked if it is determined that it is no longer in the best interests of the public health to continue the exemption.

(c) An exemption that has been revoked may be reinstated, upon request from the State or political subdivision, if the Commissioner, in accordance with the procedures in § 808.25, determines that the grounds for revocation are no longer applicable except that the Commissioner may permit abbreviated submissions of the documents and materials normally required for an application for exemption under § 808.20.

### Subpart C—Listing of Specific State and Local Exemptions

#### § 808.53 Arizona.

The following Arizona medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act:

(a) Arizona Revised Statutes, Chapter 17, sections 36–1901.7(s) and 36–1901.7(t).

(b) Arizona Code of Revised Regulations, Title 9, Article 3, sections R9–16–303 and R9–16–304.

[45 FR 67336, Oct. 10, 1980]

#### § 808.55 California.

(a) The following California medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration exempted them from preemption under section 521(b) of the act: Business and Professions Code sections 3365 and 3365.6.

(b) The following California medical device requirements are preempted by section 521 of the act, and FDA has denied them an exemption from preemption:

(1) Sherman Food, Drug, and Cosmetic Law (Division 21 of the California Health and Safety Code), sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26641, to the extent that they apply to devices.

(2) Sherman Food, Drug, and Cosmetic Law, section 26463(m) to the extent that it applies to hearing aids.

(3) Business and Professions Code section 2541.3, to the extent that it requires adoption of American National Standards Institute standards Z–80.1 and Z–80.2.

[45 FR 67324, Oct. 10, 1980]

#### § 808.57 Connecticut.

The following Connecticut medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Connecticut General Statutes, sections 20–403 and 20–404.

[45 FR 67336, Oct. 10, 1980]

#### § 808.59 Florida.

The following Florida medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act:

(a) Florida Statutes, section 468.135(5).

(b) Florida Administrative Code, section 10D–48.25(26).

[45 FR 67336, Oct. 10, 1980]